

Patent claims

1. Pharmaceutical active-ingredient-containing formulation for oral administration which is coated with a single coating of a film-forming polymer, the coating comprising a mixture of at least two separating agents and no stabilizer.
2. Formulation according to claim 1, wherein the coating does not contain surfactant or antifoam as stabilizer.
3. Formulation according to claim 1 and/or 2, wherein the film-forming polymer is characterised in that it can be provided in the form of a water-based dispersion.
4. Formulation according to at least one of the preceding claims, wherein the film-forming polymer is a mixture of film-forming polymers.
5. Formulation according to at least one of the preceding claims having a polyacrylate as film-forming polymer.
6. Formulation according to claim 5, wherein the polyacrylate is a polymer based on acrylic acid, methacrylic acid, acrylic acid ester and/or methacrylic acid ester, especially Eudragit and/or Kollicoat.
7. Formulation according to at least one of the preceding claims, wherein the mixture having the at least two separating agents comprises
  - at least one separating agent that floats in pure water, and
  - at least one separating agent that sinks in pure water.

8. Formulation according to at least one of claims 1 to 6, wherein the mixture having the at least two separating agents comprises

- at least one fatty acid salt as separating agent and
- 5 - at least one silicate from the group composed of double chain silicates and layer silicates as separating agent.

9. Formulation according to claim 7 or 8, wherein the mixture comprises as floating separating agent or as fatty acid salt an alkali metal salt and/or an alkaline earth metal salt and/or an aluminium salt of a fatty acid.

10. Formulation according to claim 9, wherein the mixture comprises sodium, potassium, magnesium and/or calcium behenate as alkali metal or alkaline earth metal salt of a fatty acid.

11. Formulation according to claim 9, wherein the mixture comprises sodium, potassium, magnesium, calcium and/or aluminium stearate as alkali metal, alkaline earth metal or aluminium salt of a fatty acid.

12. Formulation according to claim 9, wherein the mixture comprises a magnesium salt of caprylic acid, capric acid, lauric acid and/or palmitic acid as alkaline earth metal salt of a fatty acid.

13. Formulation according to at least one of claims 7 to 12, wherein the content of floating separating agent or of fatty acid salt is from 5 to 40 % by weight, preferably from 10 to 30 % by weight, in each case based on the dry weight of the film-forming polymer.

14. Formulation according to at least one of claims 7 to 13 and especially according to claim 7 and/or 8, wherein the mixture comprises a layer silicate as sinking separating agent or as silicate.

15. Formulation according to claim 14, wherein the mixture comprises talcum, kaolinite, pyrophyllite, attapulgite, sepolite, muscovite, montmorillonite, bentonite and/or vermiculite as layer silicate.

16. Formulation according to at least one of claims 7 to 15, wherein the content of sinking separating agent or of silicate is from 20 to 60 % by weight, preferably from 30 to 50 % by weight, in each case based on the dry weight of the film-forming polymer.

17. Formulation according to at least one of the preceding claims in the form of active-ingredient-containing cores provided with the coating, which are capsules, tablets, pellets, granules, minitables or micropellets.

18. Formulation according to at least one of claims 1 to 16 in the form of cores provided with the coating, which are active ingredient crystals.

19. Formulation according to claim 17, wherein an active-ingredient-containing core in the form of a pellet or micropellet comprises an inert core, an active-ingredient-containing core especially being constituted by an inert core with an active-ingredient-containing coating.

20. Formulation according to claim 17 and/or 19, wherein the micropellets are provided as multiple-unit-dosage form, especially in the form of tablets or in capsules.

5 21. Formulation according to claim 17 and/or 19, wherein the pellets, granules or minitabets are provided as multiple-unit-dosage form, especially in capsules.

10 22. Formulation according to claim 20 and/or 21, wherein the multiple-unit-dosage form is in turn provided with a coating according to at least one of claims 1 to 16.

15 23. Formulation according to at least one of claims 20 to 22, wherein the multiple-dosage form is a capsule, especially a soft gelatin capsule.

20 24. Formulation according to at least one of the preceding claims, wherein the active ingredient is provided in admixture with pharmaceutically acceptable auxiliaries, especially with customary auxiliaries.

25 25. Formulation according to at least one of the preceding claims, wherein the active ingredient is provided in admixture with surfactants, especially non-ionic or ionic surface-active substances, or is free of surfactants.

30 26. Formulation according to at least one of the preceding claims having a readily water-soluble active ingredient, preferably with a solubility of more than 300 g/l aqueous solution.

27. Formulation according to at least one of the preceding claims with metoprolol or a salt thereof as active ingredient, especially metoprolol succinate.

5 28. Aqueous dispersion for the preparation of a coating for a pharmaceutical active-ingredient-containing formulation for oral administration according to any one of the preceding claims, the dispersion having a content of a film-forming polymer and of at least two separating agents and  
10 being free of stabilizers, wherein

- at least one separating agent that floats in pure water is present in an amount of from 5 to 40 % by weight, and
- at least one separating agent that sinks in pure water  
15 is present in an amount of from 20 to 60 % by weight, in each case based on the polymer dry weight.

29. Aqueous dispersion for the preparation of a coating for a pharmaceutical active-ingredient-containing formulation  
20 for oral administration according to any one of the preceding claims, the dispersion having a content of a film-forming polymer and of at least two separating agents and being free of stabilizers, wherein

- at least one fatty acid salt is present as separating  
25 agent in an amount of from 5 to 40 % by weight, and
- at least one silicate from the group composed of double chain silicates and layer silicates is present in an amount of from 20 to 60 % by weight, in each case based on the polymer dry weight.

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30. Dispersion according to claim 28 or 29, wherein the dispersion comprises no surfactant or antifoam as stabilizer,

- in particular no non-ionic surfactant, especially no polysorbate, sorbitan monoisostearate, sorbitan mono-laurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan monooleate, sorbitan sesquioleate, sorbitan trioleate, glyceryl monostearate, glyceryl monooleate and/or polyvinyl alcohol,
- in particular no anionic surfactant, especially no sodium docusate and/or sodium lauryl sulfate,
- in particular no cationic surfactant, especially no benzalkonium chloride, benzethonium chloride and/or cetrimide,
- in particular no silicone-based antifoam and/or
- in particular no glycerol, sorbitol and/or PEG derivative as antifoam.

31. Process for the preparation of a pharmaceutical active-ingredient-containing formulation according to any one of the preceding claims, wherein a formulation that is as yet uncoated is provided with a coating using a dispersion according to any one of claims 28, 29 and 30.